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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,874	06/29/2006	Catherine Larnier	LA/3-3331 2 A	9570

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Novartis Consumer Health, Inc.
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,874	LARNIER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112 1st Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment a fungal infection or treating an infection of dermatophytes, does not reasonably provide enablement for the prevention of fungal infection or dermatophyte infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples

6. The quantity of experimentation necessary;

7. The state of the prior art; and

8. The relative skill of those skilled in the art.

Each relevant factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention and breadth of claims: the claims are drawn a method of treating or preventing of fungal infections, such as those caused by dermatophytes, by the topically application of a composition comprising terbinafine and hydrocortisone. Topically acceptable salts of the terbinafine and hydrocortisone, as well as topically acceptable esters of hydrocortisone are also encompassed by the claims.

2. The quantity of experimentation necessary, the state of the prior art, and the relative skill of those skilled in the art: The relative skill of those skilled in the art is high. "Prevent" is defined (p 3, dictionary.com entry accessed 11/28/07) as “keep from happening or arising, make impossible.” The variety of fungi can cause infections of various levels of severity in humans. Just as with viruses, even is a person does not show outward signs of an infection, they can still be infected with spores of the fungi. While the immune system may respond and prevent a widespread infection that would result in outward symptoms, the individual was still infected with a fungus. Therefore, by

a method of preventing fungal infection, the person would not only never develop outward symptoms of a fungal infection of any type but would also never be infected with any amount of fungi. As “treating” encompasses all reasonably successful therapies, the examiner recommends deleting “preventing” and “prevents” and only reciting "treating" and “treats” instead.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt (US 5,496,812) in view of Glassman (US 6,281,239).

Platt discloses a topical composition comprising the antifungal agent tolnaftate and the anti-inflammatory ingredient hydrocortisone (col 1, ln 11 – 14). The composition not only uses the antifungal and steroid for the reasons taught in the prior art, but also to provide a synergistic effect (col 3, ln 39 – 46). Other compositions comprising a steroid and an anti-fungal agent are known in the art (col 3, ln 17 – 23). Compositions comprising an anti-fungal agent and an anti-inflammatory agent are also known in the art for treating fungal infections (col 1, ln 52 – col 2, ln 2). As an over-the-counter formulation, the compositions taught by Platt includes 1.5% by weight tolnaftate and 1% by weight hydrocortisone, although in a prescription preparation, higher amounts (1.5 – 4.5% tolnaftate and 1 – 1.5% hydrocortisone) may be included in the preparation (col 4, ln 56 – 64). These preparations are used in the treatment of common fungal infections commonly known as jock itch and athlete's foot (col 4, ln 51 – 56). The vehicle system can be an emulsion or cream (col 5, ln 1 – 2) and can include topically acceptable carriers such as emollients and water (col 5, ln 6 – 14).

Platt does not disclose the inclusion of the anti-fungal agent terbinafine or terbinafine hydrochloride in the topical compositions.

Glassman discloses a combination treatment for treating fungal infection of the nail unit (col 1, ln 4 – 8). The antifungal agents may be used in methods of killing or substantially inhibiting the growth fungi such as dermatophytes (col 3, ln 35 – 44). Among the antifungal agents taught are terbinafine (col 3, ln 50) and tolnafate (col 3, ln 51).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising an antifungal agent and hydrocortisone, disclosed by Platt, and to use terbinafine as the anti-fungal agent, taught by Glassman as a functional equivalent of the tolnaftate used in the compositions of Platt. The composition can be used to treat a variety of fungal infections, such as those caused by dermatophytes.

7. Claims 1 – 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt and Glassman as applied to claims 1 – 5, 8 and 9 above, and further in view of Chodosh (US 5,661,170).

Platt and Glassman teach a topical composition comprised of terbinafine and hydrocortisone that can be used for the treatment of fungal infections.

Neither reference teaches a gel composition form.

Chodosh discloses topical compositions applied to the nails and adjacent tissue for the treatment of mycotic and bacterial infections (col 1, ln 10 – 15). Among the

suitable active agents that may be present in the composition are tolnaftate and terbinafine hydrochloride (col 3, ln 28 – 35). The composition can take a variety of forms, including ointments, salves, lotions and gels (col 7, ln 34 – 39).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the terbinafine (or terbinafine hydrochloride) and hydrocortisone topical formulation taught by Platt and Glassman as a gel, taught by Chodosh as a suitable administration form for these antifungal active agents.

8. Claims 1 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platt, Glassman and Chodosh as applied to claims 1 – 6, 8 and 9 above, and further in view of Shah et al. (US 5,219,877).

As discussed above, Platt and Glassman teach a topical composition comprising hydrocortisone and terbinafine. In addition to disclosing a gel as a suitable administration form for antifungal compositions, Chodosh also discloses the use of the hydrochloride salt of terbinafine as an antifungal agent.

Platt, Glassman and Chodosh do not teach the use hydrocortisone acetate as the form of hydrocortisone used in the composition.

Shah et al. discloses a gel formulation for topical administration (abstract). These formulations may contain hydrocortisone or hydrocortisone acetate (col 3, ln 56 – 59).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a topical composition comprising terbinafine and hydrocortisone, as taught by Platt and Glassman, and to use terbinafine hydrochloride,

taught by Chodosh as an antifungal agent, and hydrocortisone acetate, taught by Shah et al. as a functional equivalent of hydrocortisone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW